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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/541,552	Applicant(s) ZIVITZ, MAURY
	Examiner Arlen Soderquist	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 24-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 24-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-2o and 24-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parks or White (newly cited and applied) in view of Van Rooijen and Shults Newly cited and applied), Eifler, Yasuda, Tien, Raymond, Wohltjen, Stanbro or Pribat.

In the patent Parks teaches a amperometric biosensor electrode excitation circuit that is substantially similar to the claimed device. The device has two spaced apart electrodes (12,14) forming a measurement loop that includes a test cell (10) on a substrate (16). A cover sheet (18) is provided with openings (20,24) which expose electrodes. One opening (20) creates a well and defines a reaction zone between the electrodes. A gel-like layer (not shown) of reactants overlays electrodes and provides a substrate on which a subsequent analyte-containing fluid sample can be placed. Column 1, lines 23-56 describe amperometric sensors that employ the Cottrell current in measuring the amount of analyte present along with some problems associated therewith in prior devices. Each system is dependent upon a reaction an analyte such as glucose, in the presence of an enzyme, e.g., glucose oxidase, catalyzes a reaction such as potassium ferricyanide to potassium ferrocyanide. After that reaction has completed, a voltage applied across the reaction zone causes the reaction to reverse with an accompanying generation of a small, but measurable, current. That current is termed the Cottrell current and, in dependence upon the concentration of glucose in the reaction zone, will follow a predetermined curve during the reverse reaction. A reading of the Cottrell current can then be converted into

an indication of glucose concentration. Figure 3 and its associated discussion teach a circuit for applying potential to the electrodes for measurement of an analyte. Parks does not teach a noise cancellation loop to cancel the effects of electromagnetically propagated energy.

In the patent White teaches a biosensing meter substantially similar to the claimed device. Figure 1 shows the sample strip (10) having two spaced apart, electrically isolated electrodes (sense electrode 12, excitation electrode 14) forming a measurement loop that includes a reaction zone on a substrate (16). A cover sheet (18) is provided with openings (20-21) which expose the electrodes. One opening (20) creates a well and defines a reaction zone between the electrodes. A gel-like layer (not shown) of reactants overlays electrodes and provides a substrate on which a subsequent analyte-containing fluid sample can be placed. A second opening (21) exposes the electrodes so that when sample strip is inserted into a biosensing meter, electrical connection can be made thereto. When a drop of biological sample fluid is placed in the reaction zone, a plurality of fail/safe tests are performed. A drop size test is performed by a circuit that detects the size of the drop placed in the reaction zone. The circuit both detects that a drop has been placed in the reaction zone and further measures a test current level, after a delay, to determine that the drop size is sufficient to enable hydration of reactants in the reaction zone. Subsequently, during the reaction, a "delta" current change is measured at succeeding sample time. This test measures the difference between succeeding current samples during a measurement time. If each succeeding sample is not less than preceding sample by a delta value, a determination is made that the current is not monotonically decreasing and the test is aborted. At the termination of the measurement time, a current sum test is performed wherein a processor calculates a linear sum of all sample test currents and calculates a ratio between that sum and the last current sample. If that ratio matches a pre-calculated constant for the Cottrell relationship, then it is known that the measurement values exhibit the Cottrell relationship. The functioning of the device is explained with reference to a glucose sensor. The chemistries employed by this system are known in the art. Glucose concentration is determined by initially placing a sample of blood in the raction zone. The glucose within the sample causes a forward reaction of potassium ferricyanide to potassium ferrocyanide. When the forward reaction has proceeded to completion during an incubation period, a subsequent application of a voltage (trace 76) to excitation electrode will see the creation of a small current at sense electrode that

results from a reverse reaction of potassium ferrocyanide back to potassium ferricyanide. The flow of electrons during the reverse reaction (trace 78) is sensed and measured. White does not teach a noise cancellation loop to cancel the effects of electromagnetically propagated energy.

In the paper Van Rooijen discusses noise and drift phenomena in amperometric and coulometric detectors. Noise and drift phenomena in electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis are discussed. A relation between the capacity of the working electrode and the noise of the detector is demonstrated in 3 different ways, using direct correlation of noise with capacitance, time correlation functions, and electrical simulation of the cell properties. Conclusions are drawn with respect to the prospects of various measures to improve the detection limit. On page 2232 several different causes of drift and noise are listed including temperature fluctuations and the electronic equipment. In the theoretical section of the paper Van Rooijen teaches that a potential difference is applied to the electrodes followed by measurement of current or voltage depending on the type of detector.

In the paper Shults teaches a chronopotentiometer with compensation for extraneous currents. In the first paragraph Shults recognizes that although the theory of chronopotentiometric experiments is based on an assumption of all the electrolysis current being derived from the electroactive species in the sample, other processes occur concurrently. The results of chronopotentiometric experiments are complicated by the charging of the electric double layers at the electrode-solution interface, the electrolysis of minor and major components of the solution, and the electrolytic reduction or oxidation of the electrode itself, all in addition to the electroactive species of interest. These phenomena proceed at variable rates so that current efficiency for the desired electrode reaction is variable and difficult to calculate. A novel method of compensating for most of the difficulties is described wherein a 2nd electrolytic cell (second measurement loop), containing everything except the ion in question, is placed in a new type of bridge circuit with the analysis cell (first measurement loop). An uncompensated chronopotentiogram (potential difference applied to the electroactive species containing cell) for the reduction of $Fe(CN)_6^{3-}$ (ferrocyanide) is shown in figure 2 in juxtaposition to a compensated one (potential difference applied to both cells), along with an accompanying

chronoamperometric curve. The uncompensated chronopotentiogram shows a curve with a gentle inflection at the end point while the compensated curve, obtained by summing the respective currents, has a very sharp end point. The compensated curve results in the data being linear over a wide range of potentials.

Each of the Eifler, Yasuda, Tien, Raymond, Wohltjen, Stanbro or Pribat references has a primary measuring circuit in a support with two electrodes connected to a analyte detection zone for measuring an analyte and a reference measuring circuit also on the support which is electrically distinct from the analyte detection zone and physically arranged to experience the same environment as the primary measuring circuit. The reference measuring circuit is used to cancel affects such as temperature that are known to affect the measuring circuit. Because of the proximity of the reference circuit to the measuring circuit and the cancellation of electrical affects from the measuring circuit signal, the structure taught by each of Eifler, Yasuda, Tien, Raymond, Wohltjen, Stanbro and Pribat inherently cancels other affects which would cause an electrical signal in the measuring circuit other than that from the analyte being measured.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the compensating configurations of Shults, Eifler, Yasuda, Tien, Raymond, Wohltjen, Stanbro or Pribat into the Parks or White devices and methods because of the ability to remove interferences from temperature fluctuations as taught by Eifler, Yasuda, Tien, Raymond, Wohltjen, Stanbro and Pribat or other electrical current producing interactions occurring in a chronoamperometric measurement as taught by Shults which Van Rooijen and Shults teach as clearly affecting the electrochemical signal and Shults teaches as being removed or significantly reduced by the second measurement loop in a chronoamperometric measurement.

3. Applicant's arguments filed June 9, 2003 have been fully considered but they are not persuasive. Applicant argues that a the combination fails to meet the requirements for obviousness particularly with respect to the new language regarding the Cottrell current-like profile. With respect to this, both Parks and the newly cited and applied White reference teach their devices as amperometric devices including a Cottrell current-like profile in the measurement. In their devices, a sample is applied to the reagent zone causing a reversible reaction to occur when the analyte is present in the sample. After the reaction has been allowed to finish, a potential difference is applied to the two electrodes causing the reverse reaction to

occur resulting in a current (Cottrell current) being generated and measured. Both Parks and White teach potassium ferricyanide as the substance undergoing the reaction. Thus these references are clearly directed toward the claimed devices and methods. It should also be pointed out that both Parks and White are directed toward correcting problems that exist in amperometric sensor devices. The Van Rooijen reference is directed toward noise and drift phenomena in amperometric and coulometric detectors. In both of these types of detectors a potential difference is applied between a least two electrodes in the sample and current or voltage are measured. The discussion is general because all of these detectors include applying a potential difference applied between electrodes followed by measuring a current or voltage. Thus one of ordinary skill in the art would have understood the paper to be relevant to all types of amperometric detectors. In this way one of ordinary skill in the art would have expected the Parks and White detectors to suffer from the noise and drift problems discussed by Van Rooijen. The Shults reference would have been recognized as directed to a detector that is similar to the Parks and White references based on the similarity in the signal shape shown in figure 2 of Shults and figures 3 and 5 of White. Additionally the ferricyanide/ferrocyanide used as the electroactive compound in Shults is the same substance undergoing the reaction in Parks and White. From this one of ordinary skill in the art would have recognized that there are factors or processes that affect the measured current occurring simultaneously with the desired reaction. Shults clearly teaches that these things can be compensated for by a second measuring loop that is subjected to identical conditions except contact with the electroactive substance in the sample to b e measured. From this, one of skill in the art would have recognized and expected that providing a second measurement loop subject to the same conditions except for contact with the electroactive substance in the Parks and White devices would have compensated for the electrical currents due to these processes that are known to be present as shown by Shults and Van Rooijen. The Eifler, Yasuda, Tien, Raymond, Wohltjen, Stanbro and Pribat references show that a similar solution, a second measurement loop that is subject to the same conditions as the first measurement loop except for a sensitivity to or contact with the analyte, can compensate for noise or interference from temperature fluxuations. Since Van Rooijen clearly teaches that Amperometric sensors suffer from this type of noise or interference, one of ordinary skill in the art would have recognized and expected the second measurement loop to also compensate for

temperature effects as well as the processes taught by Shults. Thus there is clear and sufficient motivation for one of ordinary skill in the art to modify the Parks and White devices and methods to place a second measuring loop or a noise cancellation/compensation loop on the substrate that is electrically distinct from the analyte reaction zone and physically arranged to be exposed to substantially the same environment as the measurement loop.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art is directed to biosensors that are similar to the claimed device in that they have multiple measurement loops that are used to compensate for the presence of interfering substances or Cottrell currents in measurement devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Soderquist
August 22, 2003
ARLEN SODERQUIST
PRIMARY EXAMINER